Complete Summary

GUIDELINE TITLE

Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis.

BIBLIOGRAPHIC SOURCE(S)

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR Recomm Rep 2001 Jun 29;50(RR-11):1-52. [128 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Hepatitis B virus (HBV) infection
- Hepatitis C virus (HCV) infection
- Human immunodeficiency virus (HIV) infection (acquired immunodeficiency syndrome, AIDS)

GUIDELINE CATEGORY

Evaluation
Prevention

CLINICAL SPECIALTY

Family Practice
Infectious Diseases

Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To update and consolidate all previous United States Public Health Service (PHS) recommendations for the management of health-care personnel (HCP) who have occupational exposure to blood and other body fluids that might contain hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV).

TARGET POPULATION

Health care personnel who have occupational exposure to blood and other body fluids that may contain hepatitis B virus, hepatitis C virus, or human immunodeficiency virus (HIV).

INTERVENTIONS AND PRACTICES CONSIDERED

1. Evaluation of exposure site, risk associated with exposure, exposure source, and exposed person
2. Post-exposure prophylaxis (PEP), where exposure poses risk of infection
3. Performance of follow-up testing and counseling

MAJOR OUTCOMES CONSIDERED

- Transmission of hepatitis B virus (HBV), hepatitis C virus, and human immunodeficiency virus (HIV)
- Drug and vaccine toxicities

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The guideline updates and consolidates all previous U.S. Public Health Service recommendations for the management of health-care personnel (HCP) who have occupational exposure to blood and other body fluids that might contain hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV).

Recommendations for hepatitis B virus postexposure management include initiation of the hepatitis B vaccine series to any susceptible, unvaccinated person who sustains an occupational blood or body fluid exposure. Postexposure prophylaxis with hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine series should be considered for occupational exposures after evaluation of the hepatitis B surface antigen status of the source and the vaccination and vaccine-response status of the exposed person. Guidance is provided to clinicians and exposed health-care personnel for selecting the appropriate hepatitis B virus postexposure prophylaxis.

Immune globulin and antiviral agents (e.g., interferon with or without ribavirin) are not recommended for postexposure prophylaxis of hepatitis C. For hepatitis C virus postexposure management, the hepatitis C virus status of the source and the exposed person should be determined, and for health-care personnel exposed to an hepatitis C virus positive source, follow-up hepatitis C virus testing should be performed to determine if infection develops.

Recommendations for HIV postexposure prophylaxis include a basic 4-week regimen of two drugs (zidovudine [ZDV] and lamivudine [3TC]; 3TC and stavudine [d4T]; or didanosine [ddI] and d4T) for most HIV exposures and an expanded regimen that includes the addition of a third drug for HIV exposures that pose an increased risk for transmission. When the source person's virus is known or suspected to be resistant to one or more of the drugs considered for the postexposure prophylaxis regimen, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended.

In addition, the guideline outlines several special circumstances (e.g., delayed exposure report, unknown source person, pregnancy in the exposed person, resistance of the source virus to antiretroviral agents, or toxicity of the postexposure prophylaxis regimen) when consultation with local experts and/or the National Clinicians' Post-Exposure Prophylaxis Hotline ([PEPline] 1-888-448-4911, U.S. only) is advised.

Occupational exposures should be considered urgent medical concerns to ensure timely postexposure management and administration of hepatitis B immune globulin, hepatitis B vaccine, and/or HIV postexposure prophylaxis.

Recommendations for Health-Care Facilities Implementing the U.S. Public Health Service Guidelines for Management of Occupational Exposures to Bloodborne Pathogens

1. Establish a bloodborne pathogen policy
    - All institutions where health-care personnel might experience exposures should have a written policy for management of exposures
    - The policy should be based on the U.S. Public Health Service (PHS) guidelines
    - The policy should be reviewed periodically to ensure that it is consistent with Public Health Service recommendations
2. Implement management policies
    - Health-care facilities should provide appropriate training to all personnel on the prevention of and response to occupational exposures

- Health-care facilities should establish hepatitis B vaccination programs
- Health-care facilities should establish exposure-reporting systems
- Health-care facilities should have personnel who can manage an exposure readily available at all hours of the day
- Health-care facilities should have ready access to postexposure prophylaxis for use by exposed personnel as necessary

3. Establish laboratory capacity for bloodborne pathogen testing
    - Health-care facilities should provide prompt processing of exposed person and source person specimens to guide management of occupational exposures
    - Testing should be performed with appropriate counseling and consent
4. Select and use appropriate postexposure prophylaxis regimens
    - Health-care facilities should develop a policy for the selection and use of postexposure prophylaxis antiretroviral regimens for HIV exposures within their institution
    - Hepatitis B vaccine and hepatitis B immune globulin should be available for timely administration
    - Health-care facilities should have access to resources with expertise in the selection and use of postexposure prophylaxis
5. Provide access to counseling for exposed health-care personnel
    - Health-care facilities should provide counseling for health-care personnel who might need help dealing with the emotional effect of an exposure
    - Health-care facilities should provide medication adherence counseling to assist health-care personnel in completing HIV postexposure prophylaxis as necessary
6. Monitor for adverse effects of postexposure prophylaxis
    - Health-care personnel taking antiretroviral postexposure prophylaxis should be monitored periodically for adverse effects of postexposure prophylaxis through baseline and testing (every 2 weeks) and clinical evaluation
7. Monitor for seroconversion
    - Health-acre facilities should develop a system to encourage exposed health-care personnel to return for follow-up testing
    - Exposed health-care personnel should be tested for hepatitis C virus and HIV
8. Monitor exposure management programs
    - Health-care facilities should develop a system to monitor reporting and management of occupational exposures to ensure timely and appropriate response
        a. Evaluate
            - exposure reports for completeness and accuracy
            - access to care (i.e., the time of exposure to the time of evaluation), and laboratory result reporting time
        b. Review
            - exposures to ensure that health-care personnel exposed to sources not infected with bloodborne pathogens do not receive postexposure prophylaxis or that postexposure prophylaxis is stopped
        c. Monitor
            - completion rates of hepatitis B virus vaccination and HIV postexposure prophylaxis and completion of exposure follow-up

Management of Occupational Blood Exposures

1. Provide immediate care to the exposure site:
    - Wash wounds and skin with soap and water
    - Flush mucous membranes with water
2. Determine risk associated with exposure by:
    - type of fluid (e.g., blood, visibly bloody fluid, other potentially infectious fluid or tissue, and concentrated virus) and,
    - type of exposure (i.e., percutaneous injury, mucous membrane or nonintact skin exposure, and bites resulting in blood exposure)
3. Evaluate exposure source:
    - Assess the risk of infection using available information
    - Test known sources for Hepatitis B surface antigen, anti-hepatitis C virus, and HIV antibody (consider using rapid testing)
    - For unknown sources, assess risk of exposure to hepatitis B virus, hepatitis C virus, or HIV infection
    - Do not test discarded needles or syringes for virus contamination
4. Evaluate the exposed person:
    - Assess immune status for hepatitis B virus infection (i.e., by history of hepatitis B vaccination and vaccine response)
5. Give postexposure prophylaxis for exposures posing risk of infection transmission:
    - Hepatitis B virus: See Table 3 in the original guideline document
    - Hepatitis C virus: Postexposure prophylaxis not recommended
    - HIV: See Tables 4 and 5 in the original guideline document
    - Initiate postexposure prophylaxis as soon as possible, preferably within hours of exposure
    - Offer pregnancy testing to all women of childbearing age not known to be pregnant
    - Seek expert consultation if viral resistance is suspected
    - Administer postexposure prophylaxis for 4 weeks if tolerated
6. Perform follow-up testing and provide counseling:
    - Advise exposed persons to seek medical evaluation for any acute illness occurring during follow-up
7. Hepatitis B virus exposures:
    - Perform follow-up anti-hepatitis B surface antigen testing in persons who receive hepatitis B vaccine
    - Test for anti-hepatitis B surface antigen 1 to 2 months after last dose of vaccine
    - Anti-hepatitis B surface antigen response to vaccine cannot be ascertained if hepatitis B immune globulin was received in the previous 3 to 4 months
8. Hepatitis C virus exposures:
    - Perform baseline and follow-up testing for anti-hepatitis C virus and alanine amino- transferase (ALT) 4 to 6 months after exposures
    - Perform hepatitis C virus RNA at 4 to 6 weeks if earlier diagnosis of hepatitis C virus infection desired
    - Confirm repeatedly reactive anti-hepatitis C virus enzyme immunoassays (EIAs) with supplemental tests
9. HIV exposures:
    - Perform HIV-antibody testing for at least 6 months postexposure (e.g., at baseline, 6 weeks, 3 months, and 6 months)

- Perform HIV antibody testing if illness compatible with an acute retroviral syndrome occurs
- Advise exposed persons to use precautions to prevent secondary transmission during the follow-up period
- Evaluate exposed persons taking postexposure prophylaxis within 72 hours after exposure and monitor for drug toxicity for at least 2 weeks
- See Appendix C in the original guideline document for basic and expanded HIV postexposure prophylaxis regimens

Please see the original guideline for further details.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Animal studies and a retrospective case-control study of health care workers have provided direct and indirect evidence of the efficacy of antiviral drugs for postexposure prophylaxis. Perinatal transmission studies were another source of supporting evidence for the guideline recommendations.

Prospective studies have proven the efficacy of hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine for postexposure prophylaxis (PEP) for hepatitis B virus (HBV).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Reduced risk of hepatitis B virus following occupational exposure: In the occupational setting, multiple doses of hepatitis B immune globulin initiated within 1 week following percutaneous exposure to hepatitis B surface antigen-positive blood provides an estimated 75% protection from hepatitis B virus infection.

Prevention of chronic infection: Data from studies conducted outside the United States suggest that a short course of interferon started early in the course of acute hepatitis C is associated with a higher rate of resolved infection than that achieved when therapy is begun after chronic hepatitis C has been well established.

Reduced risk of HIV transmission following occupational exposure: In the retrospective case-control study of health care workers, after controlling for other risk factors for HIV transmission, the risk for HIV infection among health care workers who used zidovudine as postexposure prophylaxis was reduced by approximately 81% (95% CI=43%-94%)

POTENTIAL HARMS

- Side effects and toxicity of antiretroviral agents: Common symptoms reported by health care personnel receiving postexposure prophylaxis included nausea, malaise or fatigue, headache, and anorexia. Serious side effects, including nephrolithiasis, hepatitis, and pancytopenia, have been reported with the use of combination drugs for postexposure prophylaxis.
- Development of resistance to antiretroviral agents.
- Side effects of hepatitis B vaccines: The most common side effects from hepatitis B vaccination are pain at the injection site and mild to moderate fever. A less common side effect of alopecia has been observed in children and adults after administration of plasma-derived and recombinant hepatitis B vaccine. A low rate of anaphylaxis has been observed (1 in 600,000).
- Side effects of hepatitis B immune globulin (HBIG): Local pain and tenderness at the injection site, uticaria and angioedema might occur. Anaphylactic reactions, although rare, have been reported following the injection of human immune globulin (IG) preparations.

QUALIFYING STATEMENTS

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Information included in these recommendations may not represent U.S. Food and Drug Administration approval or approved labeling for the particular product or indications in question. Specifically, the terms "safe" and "effective" may not be synonymous with the Food and Drug Administration-defined legal standards for product approval.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for

Postexposure Prophylaxis. MMWR Recomm Rep 2001 Jun 29;50(RR-11):1-52. [128 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 May 15 (updated 2001 Jun)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]
Food and Drug Administration (U.S.) - Federal Government Agency [U.S.]
Health Resources and Services Administration - Federal Government Agency [U.S.]
National Institutes of Health (U.S.) - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Public Health Service (PHS) interagency working group comprising representatives of the Centers for Disease Control, the Food and Drug Administration, and the National Institutes of Health.

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Centers for Disease Control and Prevention members: Elise M. Beltrami, MD; Francisco Alvarado-Ramy, MD; Sara E. Critchley, RN; Adelisa L. Panlilio, MD, MPH.; Denise M. Cardo, MD; William A. Bower, MD; Miriam J. Alter, PhD; Jonathan E. Kaplan, MD; Boris Lushniak, MD, MPH.

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

Status information regarding this guideline is available from the AIDSinfo Web site, telephone (800) 448-0440, fax (301) 519-6616; TTY (888) 480-3739.

GUIDELINE AVAILABILITY

Electronic copies: Available from the AIDSinfo Web site.

The following HTML files are also available from the AIDSinfo Web site:

- APPENDIX A. Practice Recommendations for Health-Care Facilities Implementing the U.S. Public Health Service Guidelines for Management of Occupational Exposures to Bloodborne Pathogens.
- APPENDIX B. Management of Occupational Blood Exposures.
- APPENDIX C. Basic and Expanded HIV Postexposure Prophylaxis Regimens.

Print copies: Available from the Centers for Disease Control and Prevention, National Prevention Information Network (NPIN), P.O. Box 6003, Rockville, MD 20850. Telephone: (800) 458-5231, TTY (800)-243-7012 International number (301)-562-1098. Web site: http://www.cdcnpin.org. Requests for print copies can also be submitted via the AIDSinfo Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis tool for Palm OS* or Pocket PC. The download is available from the AIDSinfo Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 25, 1999. The information was verified by the guideline developer on June 4, 1999. The information was last updated by ECRI on September 25, 2001, in response to the June 29, 2001 update.

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